

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,)	
)	
<i>Plaintiff,</i>)	Civil Action No. 5:22-cv-05055-JFM
)	
v.)	
)	
INHANCE TECHNOLOGIES LLC,)	ORAL HEARING SCHEDULED
)	FOR 8/23/23
)	
<i>Defendant.</i>)	
)	

**INHANCE TECHNOLOGIES LLC’S OPPOSITION TO THE
UNITED STATES’ MOTION FOR PARTIAL SUMMARY JUDGMENT**

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
INTRODUCTION	1
FACTUAL BACKGROUND.....	1
PROCEDURAL BACKGROUND.....	4
STANDARD OF REVIEW	5
ARGUMENT	5
I. THIS LAWSUIT IS NOT RIPE	5
II. SUMMARY JUDGMENT IS PREMATURE AT THIS POINT	7
III. THE GOVERNMENT IS NOT ENTITLED TO SUMMARY JUDGMENT	12
A. The parties dispute whether Inhance’s fluorination process was already in use as of January 21, 2015, such that it is ineligible to be a “significant new use”	13
B. The parties dispute whether any LCPFACs that may incidentally form during Inhance’s fluorination process are impurities or byproducts.....	14
C. The parties dispute whether and when EPA provided Inhance with fair notice that the Government interprets the rule as applicable to Inhance’s fluorination process	16
CONCLUSION.....	16

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases:	
<i>AbbVie Inc. v. MedImmune Ltd.</i> , 881 F.3d 1334 (Fed. Cir. 2018)	6
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986)	5
<i>Artway v. Attorney Gen. of State of N.J.</i> , 81 F.3d 1235 (3d Cir. 1996)	12
<i>Calderon v. Ashmus</i> , 523 U.S. 740 (1998)	6, 7
<i>Club Madonna, Inc. v. City of Miami Beach</i> , 924 F.3d 1370 (11th Cir. 2019)	11
<i>Doe v. Abington Friends Sch.</i> , 480 F.3d 252 (3d Cir. 2007)	9, 10
<i>Environmental Conservation Org. v. City of Dallas</i> , 529 F.3d 519 (5th Cir. 2008)	6
<i>FCC v. Fox Television Stations, Inc.</i> , 567 U.S. 239 (2012)	16
<i>Free Speech Coal., Inc. v. Attorney Gen. of U.S.</i> , 677 F.3d 519 (3d Cir. 2012)	11
<i>Galena v. Leone</i> , 638 F.3d 186 (3d Cir. 2011)	5
<i>General Elec. Co. v. EPA</i> , 53 F.3d 1324 (D.C. Cir. 1995).....	16
<i>Graber v. Dales</i> , 511 F. Supp. 3d 594 (E.D. Pa. 2021).....	8
<i>Grooms v. PennyMac Loan Servs., LLC</i> , 2023 WL 2646921 (E.D. Pa. Mar. 27, 2023)	8
<i>Harris v. Mexican Specialty Foods, Inc.</i> , 564 F.3d 1301 (11th Cir. 2009)	11
<i>In re Avandia Mktg., Sales & Prods. Liab. Litig.</i> , 945 F.3d 749 (3d Cir. 2019)	9
<i>Kaucher v. County of Bucks</i> , 455 F.3d 418 (3d Cir. 2006)	5
<i>Killian v. McCulloch</i> , 850 F. Supp. 1239 (E.D. Pa. 1994).....	9

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
<i>Orsatti v. New Jersey State Police</i> , 71 F.3d 480 (3d Cir. 1995)	5
<i>Sixth Angel Shepherd Rescue Inc. v. Pennsylvania SPCA</i> , 2011 WL 605697 (E.D. Pa. Feb. 15, 2011)	11
<i>Sixth Angel Shepherd Rescue, Inc. v. West</i> , 477 F. App'x 903 (3d Cir. 2012)	11
<i>Step-Saver Data Sys., Inc. v. Wyse Tech., The Software Link, Inc.</i> , 912 F.2d 643 (3d Cir. 1990)	6
<i>Stilp v. Borough of W. Chester</i> , 2022 WL 3722082 (E.D. Pa. Aug. 29, 2022)	11
<i>Terson Co. v. Bakery Drivers & Salesmen Loc. 194</i> , 739 F.2d 118 (3d Cir. 1984)	11
<i>TMRJ Holdings, Inc. v. Inhance Tech., LLC</i> , 540 S.W.3d 202 (Tex. App. 2018)	13
<i>Wild Fish Conservancy v. National Park Serv.</i> , 2012 WL 6615925 (W.D. Wash. Dec. 19, 2012)	7
<i>Williams v. BASF Catalysts LLC</i> , 765 F.3d 306 (3d Cir. 2014)	7
<i>Zeuner v. McDonough</i> , 2023 WL 3868357 (E.D. Pa. June 7, 2023)	8
 Statutes:	
15 U.S.C. § 2604(a)	6
15 U.S.C. § 2604(a)(1)(A)(ii)	12
15 U.S.C. § 2604(a)(2)	13
15 U.S.C. § 2604(a)(3)(A)	3, 13
15 U.S.C. § 2604(a)(1)(B)(i)	13
15 U.S.C. § 2604(a)(3)(B)(i)	4
15 U.S.C. § 2604(a)(3)(B)(ii)(I)	4
15 U.S.C. § 2604(a)(3)(C)	4
15 U.S.C. § 2604(e)(1)(A)	4, 13
15 U.S.C. § 2618(a)(1)(A)	7
 Rules:	
Fed. R. Civ. P. 26(f)	7
Fed. R. Civ. P. 56(a)	5

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
Fed. R. Civ. P. 56(c)	8
Fed. R. Civ. P. 56(c)(1)(A)	8
Fed. R. Civ. P. 56(d)	5, 8, 9
Regulations:	
40 C.F.R. § 720.3(d)	15, 16
40 C.F.R. § 720.3(m)	14
40 C.F.R. § 721.45(d)	15
<i>Certain New Chemicals; Receipt and Status Information for January 2023,</i> 88 Fed. Reg. 10320 (Feb. 17, 2023)	3
<i>Significant New Use Rule,</i> 85 Fed. Reg. 45109 (July 27, 2020)	2, 14, 16

INTRODUCTION

The Government has brought this action against Inhance Technologies LLC in an attempt to enforce a novel interpretation of the Toxic Substances Control Act (TSCA) even before the Environmental Protection Agency (EPA) has concluded a parallel administrative proceeding examining a predicate issue that could moot this lawsuit. Now the Government seeks summary disposition of one of its claims at the pleading stage (and while Inhance’s motion to dismiss is still pending). Nothing justifies such a stark departure from regular order.

The Government’s case has a ripeness problem, as Inhance has described in its pending motion to dismiss. Inhance MTD Br. 5–10; Inhance MTD Reply Br. 1–5. The motion for summary judgment only compounds the jurisdictional defect, asking the Court to enter a declaratory judgment at once, before a scheduling order issues, before discovery occurs, and before a factual record exists.

Even beyond these procedural hurdles, summary judgment is improper because there exist a number of genuine disputes of facts material to the Government’s claims. These include whether Inhance’s fluorination process was in existence as of January 21, 2015, such that it does not qualify as a “significant new use”; whether any long-chain “PFAS” compounds (per- and polyfluoroalkyl substances) that may be formed during the Inhance fluorination process are impurities or byproducts; and whether and when the Government adequately put Inhance on fair notice that EPA would seek to apply its interpretation of the Long-Chain PFAS “Significant New Use” Rule (SNUR) to Inhance’s fluorination technology.

FACTUAL BACKGROUND

Inhance provides “barrier protection” and other surface fluorination technologies that transform customers’ conventional plastics into high-performance materials. Iyer Decl. ¶ 5.

Inhance’s fluorination technology treats high-density polyethylene (HDPE) containers and fuel tanks. Iyer Decl. ¶ 13; Ex. 12. During this process, these articles are placed in one of Inhance’s fluorination chambers and exposed to fluorine and inert gas under specified parameters. Iyer Decl. ¶ 13; Ex. 16. Any long-chain perfluoroalkyl carboxylates (also referred to as “LCPFACs” or “long-chain PFAS”) present in the fluorination process are therefore not produced during the manufacture, processing, use, or disposal of another chemical substance or mixture. Iyer Decl. ¶ 20; Ex. 4. In addition, any LCPFACs that may be unintentionally formed during fluorination cannot be separated from the fluorinated article during the fluorination process. *Id.*

Inhance has been using its current technology for fluorinating fuel tanks, fuel storage containers, and HDPE plastic containers for over four decades. Iyer Decl. ¶ 8. Inhance—formerly Fluoro-Seal International—began fluorinating in 1983. Today, Inhance has 10 facilities across the United States, including facilities in West Chicago, Illinois, and Allentown, Pennsylvania, that fluorinate containers and fuel tanks. Iyer Decl. ¶ 9; Ex. 16. The fluorination technology has not changed in any material way since then. *Id.* EPA visited the West Chicago facility in 2014, as an information-gathering exercise. *See* Iyer Decl. ¶ 27. EPA raised no concerns about Inhance’s fluorination technology following the visit. *Id.*

In 2015, EPA began its rulemaking process for the Significant New Use Rule (SNUR), which was finalized in July 2020. *See* 85 Fed. Reg. 45109, 45116 (July 27, 2020). Although EPA specifically identified a number of manufacturing processes as targeted by the new rule during the five-year rulemaking, EPA did not identify fluorination of containers as a targeted use, in either the proposed rule or the final rule. Exs. 5, 7. Inhance continued to operate for over 18 months following publication of the Final Rule, with no objection by EPA. *See* Iyer Decl. ¶ 35.

Then, in January 2021, EPA issued a subpoena seeking information related to Inhance’s

fluorination processes, to which Inhance promptly responded. Iyer Decl. ¶ 37; Ex. 17.

In March 2022, EPA's enforcement office sent a Notice of Violation to Inhance, alleging for the first time that Inhance's fluorination process produces PFAS and is therefore subject to the Significant New Use Rule. Decl. ¶ 35; Ex. 18 (Notice of Violation Letter). Two weeks later, EPA's enforcement office issued an open letter to industry, asserting for the first time publicly that the rule applied to the fluorination industry. Decl. ¶ 38; Ex. 19 (Letter from Dr. Tala R. Henry, Deputy Director, Office of Pollution Prevention & Toxics (Mar. 16, 2022)). Inhance continued to provide additional information to the agency through February 2023. Iyer Decl. ¶ 37.

Although Inhance has consistently maintained that TSCA does not require Significant New Use Notices (SNUNs) for its particular use, Inhance submitted SNUNs to EPA under protest in November 2022. Gov. SUMF ¶ 17; Iyer Decl. ¶ 39; Exs. 3, 4. In December 2022, Inhance resubmitted the SNUNs to EPA. Iyer Decl. ¶ 40; Ex. 8 (*Certain New Chemicals; Receipt and Status Information for January 2023*, 88 Fed. Reg. 10320, 10323–24 (Feb. 17, 2023)). In both notices, Inhance preserved its position that the Inhance fluorination process is not subject to the Significant New Use Rule. Specifically, Inhance stated in the notices: “The Company is submitting the SNUNs to address allegations of noncompliance with the LCPFACs SNUR made by EPA. The SNUNs are neither an admission of fact nor agreement that the SNUR is legally applicable to the Company's fluorination of HDPE containers.” Ex. 3 (Preliminary Statement).

EPA has not yet completed its administrative review of the information Inhance submitted to the agency. Gov. SUMF ¶ 22. EPA's administrative process will assess the risk, if any, posed to the environment and human health by Inhance's fluorination process. At the end of its review, EPA may conclude “that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2604(a)(3)(A).

Alternatively, the agency may conclude the substance or significant new use “is not likely to present an unreasonable risk of injury to health or the environment.” § 2604(a)(3)(C). And finally, should EPA conclude that the available information is “insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use,” § 2604(a)(3)(B)(i)—or if “in the absence of sufficient information to permit the Administrator to make such an evaluation,” EPA believes the substance “may present an unreasonable risk of injury to health or the environment,” § 2604(a)(3)(B)(ii)(I)—the Administrator may take steps to “prohibit or limit” certain activities by the substance’s manufacturer “to the extent necessary to protect against an unreasonable risk of injury to health or the environment,” § 2604(e)(1)(A).

PROCEDURAL BACKGROUND

The Department of Justice initiated this action against Inhance in this Court on December 19, 2022—while EPA’s administrative process was still under way—seeking declaratory and injunctive relief for purported violations of TSCA. ECF No. 3. Two nonprofit organizations and a private citizen subsequently intervened as plaintiffs, bringing nearly identical claims. ECF No. 36.

In February 2023, Inhance moved to dismiss the Government’s and the Intervenor-Plaintiffs’ Complaints, explaining that this case is not yet ripe for judicial review and that TSCA’s “Significant *New Use*” Rule does not apply to a *decades-old* use. ECF Nos. 10, 40. Inhance’s motions remain pending.

The Government has now moved for partial summary judgment on its claim for declaratory relief (but not its claim for injunctive relief). ECF No. 37. In support, the Government argues that it is entitled to a judgment declaring Inhance liable for purported violations of TSCA. Gov. SJ Mem. 2. Specifically, the Government argues that the “undisputed facts” demonstrate that Inhance

“unlawfully manufactured” PFAS that are “subject to” the Significant New Uses Rule “before submitting the required” notices. *Id.* at 1.

The Government’s motion skips over the most critical question in this case: whether Inhance’s fluorination process is subject to the notice requirement in the first place. There are a myriad of disputed facts material to that inquiry.

STANDARD OF REVIEW

Summary judgment is proper only “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A dispute is “genuine” if there is evidence from which a reasonable factfinder could find for the non-moving party, and a dispute is “material” if it might affect the outcome of the case under governing law. *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The court views the evidence in the light most favorable to the non-moving party. *Galena v. Leone*, 638 F.3d 186, 196 (3d Cir. 2011).

“Similarly, summary judgment is improper so long as the dispute over the material facts is genuine.” *Orsatti v. New Jersey State Police*, 71 F.3d 480, 482 (3d Cir. 1995). And when the non-movant shows that its opposition depends on information absent from the record before the court, Rule 56(d) requires that summary judgment “be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition.” *Liberty Lobby, Inc.*, 477 U.S. at 250 n.5.

ARGUMENT

Inhance incorporates by reference the arguments advanced in its opposition to the Intervenor’s motion for summary judgment, including the exhibits referenced therein. Inhance further opposes the Government’s motion for summary judgment for the reasons that follow.

I. THIS LAWSUIT IS NOT RIPE.

As Inhance has explained in its motion-to-dismiss briefing (ECF No. 10-1 at 7–8; ECF No. 27 at 1–2), EPA is presently conducting an administrative proceeding in which it is considering what, if any, conditions the agency might seek to impose on Inhance’s fluorination technology—or alternatively, whether Inhance’s fluorination activities must cease entirely. Inhance MTD Br. 7–8. That administrative review process has not concluded—a fact the Government concedes. Gov. SUMF ¶ 22 (“EPA has not yet issued determinations under 15 U.S.C. § 2604(a) on any of Inhance’s SNUN submissions.”). And the outcome of the administrative process very well could moot this lawsuit; there would be nothing for this Court to enjoin if Inhance is operating in compliance with the agency’s mandate. *See, e.g., Environmental Conservation Org. v. City of Dallas*, 529 F.3d 519, 529 (5th Cir. 2008) (citizen suit seeking enforcement of Clean Water Act mooted by resolution of administrative proceeding). For this reason, and as Inhance has separately explained, the case remains unripe for review and should be dismissed.

This is particularly true as to the claim for declaratory relief that forms the basis for the Government’s partial summary motion. To decide whether a claim for declaratory relief is ripe for resolution, the Third Circuit looks to three basic factors: “[1] the adversity of the interest of the parties, [2] the conclusiveness of the judicial judgment and [3] the practical help, or utility, of that judgment.” *Step-Saver Data Sys., Inc. v. Wyse Tech., The Software Link, Inc.*, 912 F.2d 643, 647 (3d Cir. 1990). The Government’s claim for declaratory relief is not ripe because a win in court would not conclusively resolve the existing dispute and would lack practical effect, for all the reasons spelled out in Inhance’s motion to dismiss.

The Supreme Court has rejected comparable claims for declaratory relief as naked “attempts to gain a litigation advantage by obtaining an advance ruling on an affirmative defense.”

Calderon v. Ashmus, 523 U.S. 740, 747 (1998). Far from hortatory dicta, “[t]his principle is an application of Article III’s case-or-controversy requirement in the declaratory-judgment context.” *AbbVie Inc. v. MedImmune Ltd.*, 881 F.3d 1334, 1337 (Fed. Cir. 2018). The Third Circuit has adopted the rule as well, holding that “[u]nder Article III, plaintiffs may not seek a judgment that ‘would merely determine a collateral legal issue governing certain aspects of their pending or future suits.’ ” *Williams v. BASF Catalysts LLC*, 765 F.3d 306, 328 (3d Cir. 2014) (quoting *Calderon*, 523 U.S. at 747). Here, there is both a pending and potential future suit involving the issue of statutory liability, as TSCA authorizes parties subject to EPA’s adjudications to obtain direct review in the court of appeals. *See* 15 U.S.C. § 2618(a)(1)(A). And here, as in *Williams*, “the plaintiff asks the trial court to determine in part what would be litigated in full on a later date.” *Williams*, 765 F.3d at 328.

A declaratory judgment cannot issue in this posture.

II. SUMMARY JUDGMENT IS PREMATURE AT THIS POINT.

There also is a more practical problem with the Government’s motion: It comes too early in the case. The Government does not cite any case in which a court has awarded partial summary judgment on liability without the benefit of either a completed administrative agency process or a fully developed factual record. For good reason. The claims at issue in the Government’s lawsuit are premised on a number of key (and complicated) factual issues; they are not susceptible to resolution on summary judgment before a scheduling order has even issued in the case.

As this Court’s rules recognize, a summary-judgment motion is rarely appropriate at such an early phase of litigation. “Absent leave, a party is entitled to file only one single Rule 56 motion (typically *at the time designated in the scheduling order*).” Judge John F. Murphy’s Policies and Procedures ¶ 9 (emphasis added). No scheduling order has issued, and the Court has not directed

the parties to hold a Rule 26(f) conference. Kushner Decl. ¶ 7. The Government has thus “filed one of the most difficult types of summary judgment motions on which a moving party can prevail: a procedurally early motion for summary judgment on claims that they bear the burden of proof at trial.” *Wild Fish Conservancy v. National Park Serv.*, No. C12-5109 BHS, 2012 WL 6615925, at *2 (W.D. Wash. Dec. 19, 2012).

Under Rule 56, the party moving for summary judgment must support its motion with “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials.” Fed. R. Civ. P. 56(c)(1)(A). The record contains next to none of this information. Given the timing of the motion, that is not a surprise. No depositions have been taken, no documents have been produced in discovery, and no electronically stored information has been exchanged. Kushner Decl. ¶¶ 7, 11–14. The Government can only lay claim to the catch-all “other materials” category of Rule 56(c), which in this case largely consists of communications between Inhance and EPA over the course of the agency’s administrative proceeding. But that record is incomplete; Inhance does not yet have access to the full administrative record before EPA.

Summary judgment also is inappropriate under Rule 56(d), pursuant to which a court may deny or defer a motion for summary judgment when the non-moving party “cannot present facts essential to justify its opposition.” Fed. R. Civ. P. 56(d). This Court has denied motions for summary judgment where the non-moving party “has not been provided the opportunity to conduct *any* discovery,” reasoning that the non-movant is “entitled to present evidence to properly oppose” a motion for summary judgment. *Graber v. Dales*, 511 F. Supp. 3d 594, 600 (E.D. Pa. 2021). *See also, e.g., Zeuner v. McDonough*, No. CV 22-2381, 2023 WL 3868357, at *4 n.1 (E.D. Pa. June

7, 2023) (citing Rule 56(d) declaration in denial of summary judgment where “exhibits submitted by the parties” were not “particularly enlightening in the absence of a full evidentiary record”); *Grooms v. PennyMac Loan Servs., LLC*, No. CV 22-3386, 2023 WL 2646921, at *6 n.9 (E.D. Pa. Mar. 27, 2023) (The “summary judgment motion is also denied because it is premature. This case is still at the pleadings stage, and there is not yet a factual record developed.”); *Killian v. McCulloch*, 850 F. Supp. 1239, 1256 (E.D. Pa. 1994) (“[W]hen the non-moving party has not had the opportunity to discover evidence essential to his opposition, the court should deny premature motions for summary judgment.”).

“It is well established that a court is obliged to give a party opposing summary judgment an adequate opportunity to obtain discovery . . . This is necessary because, by its very nature, the summary judgment process presupposes the existence of an adequate record.” *Doe v. Abington Friends Sch.*, 480 F.3d 252, 257 (3d Cir. 2007). This is especially true because much of the relevant information is “under control of the party moving for summary judgment”—here, the Government—and Inhance has had no opportunity to obtain that information through discovery. *See In re Avandia Mktg., Sales & Prods. Liab. Litig.*, 945 F.3d 749, 761 (3d Cir. 2019). And while the Government seeks summary judgment by relying on a mishmash of documents gleaned from EPA’s administrative proceeding, discovery is the only vehicle through which Inhance can obtain the documents and information it needs under Rule 56. Kushner Decl. ¶¶ 10, 15. Circuit precedent leaves little doubt that the Rule 56(d) requirement has teeth. *Abington Friends*, 480 F.3d at 258–259 (vacating and remanding grant of summary judgment because non-moving parties were not given an “opportunity to marshal facts in aid of their argument” and “should have been allowed some measure of discovery before summary judgment was entered”).

Absent discovery, Inhance cannot access a number of critical facts essential to justify its

opposition to the Government’s motion for summary judgment. *See* Kushner Decl. ¶ 10. For example, Inhance lacks information about EPA’s knowledge about Inhance’s fluorination of polyolefin containers and fuel tanks, including when and what the agency knew vis-à-vis the issuance of the SNUR. Inhance does not have information or documents related to the knowledge of Inhance’s fluorination process that EPA may have gained when agency officials toured Inhance’s facilities.

Inhance also lacks other critical information and documents bearing directly on its defense, which includes information regarding EPA’s interpretation of the SNUR and its application to the fluorination industry prior to March 2022—when EPA first put Inhance and the industry on notice that the SNUR applied to the fluorination of the containers. Inhance also does not have any information regarding the agency’s decision not to use the North American Industrial Classification System (“NAICS”) code for an industry belonging to the same economic sector/subsector as Inhance when it issued the proposed and final SNUR, as it customarily does to notify the regulated industry of a new SNUR. Iyer Decl. ¶¶ 30–32. Inhance similarly lacks access to communications EPA had with any state regulatory agencies, including the communications referenced in the Government’s Complaint, ¶¶ 33–34, regarding the Anvil 10+10 studies or other studies related to the presence of PFAS in polyolefin containers or fuel tanks. Discovering this information is likely to support Inhance’s position that it lacked fair notice of the Government’s interpretation of the SNUR. Whereas pre-discovery summary judgment briefing can only speculate about these questions, “discovery digs subsurface and may unearth facts that tend to support” Inhance’s position. *Abington Friends*, 480 F.3d at 259.

For its part, the Government asserts that the parties possess “all necessary evidence concerning the material facts” and that “no discovery is needed for this Court to enter a declaratory

judgment in favor of the government.” Gov. SJ Mem. 2. That statement is equal parts wrong and irreconcilable with the position the Government has previously staked out in this litigation. In its opposition to Inhance’s motion to dismiss, the Government argued not only that discovery was necessary to probe “Inhance’s continuing violations of TSCA,” but that discovery should begin *even before the Court rules on the motion to dismiss*. ECF No. 25 at 1–2.

The Government also has characterized Inhance’s statutory argument as an “as-applied challenge” to the statute, *id.* at 1, 16 n.10, which by its nature involves a factual analysis. *See Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301, 1308 (11th Cir. 2009).¹ A “facial challenge” to a statute, which raises a “purely legal argument” against a law, “does not rely on a developed factual record” and therefore may often be resolved without discovery. *Club Madonna, Inc. v. City of Miami Beach*, 924 F.3d 1370, 1380 (11th Cir. 2019). By contrast, an as-applied challenge like the one Inhance brings “necessarily requires the development of a factual record for the court to consider.” *Harris*, 564 F.3d at 1308. *See also Sixth Angel Shepherd Rescue Inc. v. Pennsylvania SPCA*, No. CIV.A. 10-3101, 2011 WL 605697, at *7 (E.D. Pa. Feb. 15, 2011), *aff’d sub nom. Sixth Angel Shepherd Rescue, Inc. v. West*, 477 F. App’x 903, 907–908 (3d Cir. 2012). If the Government’s case is not dismissed, Inhance’s as-applied challenge “may not be addressed until a factual record has been developed.” *Terson Co. v. Bakery Drivers & Salesmen Loc. 194*, 739 F.2d 118, 121 (3d Cir. 1984). Discovery permits the development of that factual record in cases involving as-applied challenges. *Free Speech Coal., Inc. v. Attorney Gen. of U.S.*, 677 F.3d 519, 533–537 (3d Cir. 2012); *Stilp v. Borough of W. Chester*, No. CV 21-3989, 2022 WL 3722082,

¹ Inhance accepts the Government’s framing of its statutory argument as an “as-applied challenge” for purposes of briefing this motion. Inhance maintains that the Complaint fails to state a claim under TSCA, as explained in its motion-to-dismiss briefs. Inhance MTD Br. 10–12; Inhance MTD Reply Br. 5–8.

at *3 (E.D. Pa. Aug. 29, 2022). The Court cannot “make complex and important determinations in a factual vacuum.” *Artway v. Attorney Gen. of State of N.J.*, 81 F.3d 1235, 1250 (3d Cir. 1996). To adequately assess the merits of Inhance’s statutory challenge on summary judgment, “a developed record” must be available. *See id.* (district court’s decision to grant declaratory relief on summary judgment, without discovery, was supported by “almost no factual grounding on which to make an assessment about” statutory provision “as applied to” the challenger).

Finally, the Government attempts to justify bypassing discovery by emphasizing that TSCA is a strict-liability statute. Gov. SJ Mem. 13–14. But Inhance argues that the SNUR requirements do not reach its conduct at all. To assess that defense, the court must evaluate a number of factual issues relating the specific fluorination technology at issue. Inhance is subject to the legal provisions that it is accused of violating if—and only if—the facts line up in the Government’s favor on a number of key issues: for example, the use is actually a “new” one, the technology is applied to a chemical substance rather than an article, the substance involved is a “byproduct” and not an “impurity,” and the Government has provided fair notice of its positions. Whether the rule applies in the first place is a separate question from whether the Government can show that a party *properly* subjected to a statutory scheme has satisfied a scienter requirement. Invoking the strict-liability standard therefore profits the Government nothing.

III. THE GOVERNMENT IS NOT ENTITLED TO SUMMARY JUDGMENT.

Summary judgment also cannot be granted because there exist a number of genuine issues of material fact that preclude summary judgment in the Government’s favor. Even without the benefit of discovery, the parties dispute numerous facts including: (1) whether Inhance’s use of its fluorination technology was ongoing as of January 21, 2015, the date the SNUR was proposed; (2) whether any long-chain PFAS formed during the course of fluorination constitutes an impurity

exempt from regulation or a byproduct subject to regulation; and (3) whether and when the Government provided Inhance with fair notice that the Government would seek to apply its interpretation of the SNUR to Inhance’s fluorination technology.

TSCA authorizes EPA to regulate the manufacturing or processing of any chemical substance for “a use which the Administrator has determined . . . is a *significant new use*.” 15 U.S.C. § 2604(a)(1)(A)(ii) (emphasis added). Before EPA can exercise that authority, the Administrator must designate through notice-and-comment rulemaking “that a use of a chemical substance is a significant new use with respect to which notification is required . . . after a consideration of all relevant factors.” § 2604(a)(2).

A manufacturer who wishes to process or manufacture a chemical for a “significant new use” may “submit[] to the Administrator, at least 90 days before such manufacture or processing, a notice . . . of such person’s intention.” § 2604(a)(1)(B)(i). The Office of Chemical Safety and Pollution Prevention (OCSPP) must review that notice and determine whether the “significant new use presents an unreasonable risk of injury to health or the environment.” § 2604(a)(3)(A). After that review process is complete, the OCSPP can “issue an order . . . to prohibit or limit the . . . processing” of the substance, including placing conditions on processing. § 2604(e)(1)(A).

In its motion, the Government argues that Inhance has violated TSCA in two ways: by failing to timely submit the required notice, and by continuing to fluorinate containers before the administrative process before EPA has concluded. Gov. SJ Mem. 17. But the Government glosses over an important issue: Inhance disputes that its fluorination technology is subject to the SNUR in the first place. Inhance submitted its notice to EPA only under protest, while preserving its position that its fluorination technology is not subject to the SNUR’s notice requirements. Iyer Decl. ¶ 39; Ex. 3. A number of key facts material to that issue are disputed, including the

following:

A. The parties dispute whether Inhance’s fluorination process was already in use as of January 21, 2015, such that it is ineligible to be a “significant new use.”

Under the SNUR, uses that predate the publication of the proposed rule (i.e., January 21, 2015) are “ongoing” uses that do not require the submission of a SNUN, while uses occurring after that date are deemed “new”—and thus subject to the rule. 85 Fed. Reg. at 45116.

Inhance’s fluorination process has been ongoing since 1983—over thirty years before EPA first proposed the long-chain PFAS rule. Iyer Decl. ¶ 9; Exs. 1, 14. *See also TMRJ Holdings, Inc. v. Inhance Tech., LLC*, 540 S.W.3d 202, 205 (Tex. App. 2018) (explaining that Inhance has been in the “surface-fluorination business” since the early 1980s).

The Government has refused to acknowledge that Inhance was engaged in its current fluorination process before January 21, 2015.² The Government states only that “Inhance has fluorinated containers since at least September 25, 2020.” Gov. SJ Mem. 8; Gov. SUMF ¶ 21. That is when the final rule took effect, to be sure, but it is not the date that matters for determining an ongoing versus new use: The final rule applies to any “use not ongoing as of January 21, 2015, the date on which the proposed rule was published.” 85 Fed. Reg. at 45115.

B. The parties dispute whether any LCPFACs that may incidentally form during Inhance’s fluorination process are impurities or byproducts.

A key factual issue in this case will be whether any LCPFAC generated during the Inhance fluorination process is an “impurity” or a “byproduct.” An impurity is a “chemical substance which is unintentionally present with another chemical substance.” 40 C.F.R. § 720.3(m). A byproduct, by contrast, is “a chemical substance produced without a separate commercial intent

² As Inhance noted in its motion to dismiss, the Government failed to allege in its Complaint facts demonstrating that the Inhance fluorination process was “new”—that is, not ongoing—at the time of the proposed rule. ECF No. 10-1 at 10–13. For that reason, the Complaint should be dismissed. At minimum, though, the Government is not entitled to summary judgment on this issue.

during the manufacture, processing, use, or disposal of another chemical substance or mixture.” 40 C.F.R. § 720.3(d). Unlike byproducts, impurities are not subject to the notification requirements under the Significant New Use Rule. 40 C.F.R. § 721.45(d). This exemption applies to entities who “*manufacture[] . . . or process[]* the substance only as an impurity.” *Id.* (emphasis added). That precisely describes how any LCPFACs unintentionally form as a result of Inhance’s fluorination technology. The Government cannot now attempt to backtrack from that clear regulatory exemption by impermissibly narrowing its scope.

In its Significant New Use Notices, Inhance asserted that any LCPFACs formed during the course of fluorination were impurities, as defined by TSCA’s implementing regulations. *See* Iyer Decl. ¶ 41; Ex. 4. In its motion, the Government contests this point, arguing that the LCPFACs are byproducts—and mistakenly claims that “Inhance itself concedes that it produces long-chain PFAS as a byproduct.” Gov. SJ Mem. 15. But Inhance has never conceded this point, as the notices show. *See generally* Exs. 3, 4. To the contrary, the company has consistently maintained that the LCPFACs are impurities, while arguing in the alternative that the substances may *also* be viewed as both simultaneously. *See* Ex. 4 (Statement on the Presence of SNUN Substances in Fluorinated HDPE Containers). The Premanufacture Notices Inhance submitted as part of its notices reflect this position, as Inhance marked PFAS species as both impurities and byproducts. *See, e.g.,* Exs. 3, 4.

Whether the LCPFACs are impurities or byproducts presents an issue of material fact: If Inhance is right that the LCPFACs are impurities, the SNUR does not apply, and Inhance may not be held liable for its alleged violation. 40 C.F.R. § 721.45(d). And whether the substances at issue are impurities or byproducts hinge on a number of narrow disputed factual issues, including whether the chemical substances are unintentionally present with another chemical substance,

whether the chemical substances are produced with a “separate commercial intent,” and whether the chemical substances are produced during the manufacture, processing, use, or disposal of another chemical substance. *See* 40 C.F.R. § 720.3(d), (m); Ex. 10 (EPA, *2020 Chemical Data Reporting Byproducts, Impurities, and Recycling Scenarios* (July 2020) (EPA guidance providing numerous fact-dependent hypotheticals to assist regulated community understand similar byproduct and impurity exemptions under Chemical Data Reporting rule)).

C. The parties dispute whether and when EPA provided Inhance with fair notice that the Government interprets the rule as applicable to Inhance’s fluorination process.

The Government must provide fair notice of its interpretations of both the statute and the rule in advance of seeking to impose civil or criminal liability on a member of the regulated public. *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328–29 (D.C. Cir. 1995); *see also FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (“A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.”).

The Government now contends that Inhance should be penalized for purported violations of TSCA that predate any fair notice from EPA that Inhance’s processes could be regulated by the rule. Gov. SJ Mem. 14–16. That is not permissible under the fair notice doctrine.

In the rulemaking itself, EPA said nothing about fluorination of containers. *See* 85 Fed. Reg. 45109. The agency did not provide any guidance on the issue until it issued a notice of violation to the company years later, in March 2022, *see* Ex. 16 (Notice of Violation Letter). EPA issued an open letter to the industry two weeks later, asserting for the first time that the rule applied to the fluorination industry. Iyer Decl. ¶ 38; Ex. 17. Inhance moved quickly to obtain the necessary information to prepare its SNUNs and submitted the relevant notice shortly thereafter. Iyer Decl. ¶¶ 39–40; Exs. 3, 4.

Whether and when the Government provided Inhance with fair notice of the Government’s

interpretation of the rule as applying to fluorination of containers is highly relevant to Inhance's fair notice defense. It also is highly relevant to fashioning an appropriate declaratory remedy. Summary judgment therefore is inappropriate before the parties have had the chance to take discovery on this critical issue.

CONCLUSION

For all of the foregoing reasons, as well as those in Inhance's brief in opposition to the Intervenor's motion for summary judgment and the supporting exhibits referenced therein, summary judgment in favor of the Government is inappropriate and should be denied.

Respectfully submitted,

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Dated: June 30, 2023

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